Australian Government
Department of Health
Therapeutic Goods Administration

Guidance on the regulation of listed disinfectants in Australia

For consultation

December 2018

TGA Health Safety Regulation

Confidentiality

All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

Introduction

Please note

For the purpose of this consultation version of the guidance, the future Therapeutic Goods Order (TGO) is referred to as **TGO X**. When the new TGO is finalised and assigned a number, this will be updated.

Hospital grade and commercial/household grade disinfectants, including disinfectant wipes and surface sprays must meet the requirements of TGO X.

Sanitisers and sanitary preparations must meet the labelling requirements of TGO X.

Please see TGO X for definitions of these products.

Note

If you have a problem with an exempt disinfectant, please tell us about it at Report a medical device adverse event (medical device user).

It is an offence to import and/or supply therapeutic goods in Australia that do not conform with a standard applicable to the goods (refer sections 14 and 14A of the *Therapeutic Goods Act 1989*).

Related guidance and legislation

The Therapeutic Goods Administration (TGA) is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods. Hard surface disinfectants are regulated by the TGA and form part of the category of therapeutic goods known as 'other therapeutic goods'. The regulatory requirements for the supply of hard surface disinfectants to the public are currently set out in the:

- *Therapeutic Goods Act 1989* (the Act)
- *Therapeutic Goods Regulations 1990* (the Regulations)
- Therapeutic Goods Advertising Code*
- Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991
- Therapeutic Goods Order 54: Standards for Disinfectants (TGO 54); and
- Therapeutic Goods Order 37: General Requirements for Labels for Therapeutic Devices (TGO 37).

*The Therapeutic Goods Advertising Code 2015 will be replaced by the Therapeutic Goods Advertising Code (No. 2) 2018 from 1 January 2019.

Regulatory requirements

This guidance does not cover sponsor transfers and/or change of sponsor's name. The requirements related to sponsor transfers are set out to Regulation 10F of the *Therapeutic Goods Regulations 1990*, and our guidance on Sponsor transfer and change of sponsor name amendments.

You should also ensure that your product(s) (where applicable) meet the requirements under:

- The Poisons Standard (the SUSMP)
- The Australian Dangerous Goods Code

Poisons which are packed and sold solely for industrial, manufacturing, laboratory or dispensary use are exempt from all labelling requirements included in the SUSMP as they are covered by Safe Work Australia's National Code of Practice for the Labelling of Workplace Substances.

Basic requirements

All listed disinfectants must meet the regulatory requirements as outlined above. Before you make an application to list your disinfectant, you should ensure that you have the following information available as it may be requested by the TGA at any point in time:

- The intended use of the disinfectant
- A common name and trade name for the product
- Presentation as stated on the label (example, 1 litre, etc.)
- Name and address for all manufacturers involved in the process of producing the disinfectant and the ability to identify which steps in the production each manufacturer is responsible for
- Information relating to the formulation of ingredients including fragrance and colourants
- Microbial efficacy data
- Stability data to the extent that it is available. If you are asked to provide stability data and this information is not complete, you will need to supply preliminary stability data and indicate the protocol to be used for monitoring product performance until a final shelf life determination is made. Your approach will need to be consistent with Schedule 2 of the proposed TGO X.
- Toxicity data, where appropriate.

Note

If your product contains a new ingredient or makes new specific claims, the TGA will evaluate your application and you will be required to supply the documents as outlined above.

Formulation

Ingredients included in the formulation of therapeutic goods supplied in Australia must be identified using the relevant Australian approved names.

Australian approved names (AAN)

The TGA develops and maintains approved terminology to ensure accuracy and consistency of the information about goods on the Australian Register of Therapeutic Goods (ARTG).

These approved terms are to be used in:

- applications to register or list a good on the ARTG
- labels and packaging for therapeutic goods, and
- Product Information documents provided with the goods.

Approved terminology must be used to identify ingredients in your listed disinfectant when you submit your application through the TGA Business System (TBS). More information about accessing the relevant approved names for the individual ingredients in your formulation is available in the “Making an application” section of this guidance.

Note

You are able to apply for an Australian Approved Name for a chemical substance at Report a medical device adverse event (medical device user).

Proprietary ingredients

Proprietary ingredients are entered into the TGA Business System (TBS) by the TGA, using details submitted by the supplier of the ingredient or by a medicine sponsor (on behalf of the supplier) using the Notification of a new proprietary ingredient form. This allows for the capture of complex formulation details and other relevant information, and the provision of a unique name and number. Sponsors may select proprietary ingredients using the assigned ingredient ID number for use in their application for a listed disinfectant.

Proprietary ingredient formulations are usually fragrances or colouring ingredients.

Microbial efficacy

You will need to adhere to the test requirements as set out in TGO X in order to demonstrate microbial efficacy. If requested, you will need to provide all test methodologies and results – a summary will be insufficient. Full test methodologies and results will need to be in English with clear indexing and organisation. A summary of tests and results in English is not acceptable.

Toxicity

Manufacturers must take reasonable steps to ensure their product is safe when used as intended or when accidental contact with the product is made. Toxicity tests on disinfectants used on surfaces should clearly identify any potential hazards to the user through accidental body contact. These hazards must be clearly identified in the labelling and the product information. It is expected that toxicity data will relate to the individual components of a formulation rather than the formulation itself.

Manufacturers should consider the following when determining toxicity of their product:

- Cytotoxicity
- Acute oral toxicity

- Inhalation toxicity
- Skin irritation
- Sensitisation
- Eye irritation
- Haemocompatibility
- Sub-chronic toxicity
- Mutagenicity
- Carcinogenicity
- Environmental toxicity
- Any other known toxicity of an active ingredient or where the basic poisons related safety information suggests other forms of toxicity not mentioned above may be a hazard (e.g. neurotoxicity).

Basic poisons related safety information is required for all disinfectants. Additional information should also be supplied for the following, where applicable:

- **Acute Oral toxicity**: Additional information on acute oral toxicity should be collected unless it can be shown that the disinfectant is unlikely to be used in a way that will cause it to contact the digestive tract. The information should relate to tests conducted at concentrations equivalent to those likely to be encountered in use.
- **Inhalation toxicity, skin irritation, sensitisation and eye irritation**: Additional information on residue tests should be collected unless it can be shown that the disinfectants or their residues are unlikely to come into contact with skin, mucous membrane or eyes. The basic poisons related safety information is that which would satisfy the Poisons Standard or Material Safety Data Sheet (MSDS) requirements of the Worksafe Australia National Code for the labelling of workplace substances.
- **Haemocompatibility, sub-chronic toxicity, mutagenicity and carcinogenicity**: Information is required only if the disinfectant or its residues are likely to come into contact with intact tissue.
- **Environmental toxicity**: Ecotoxicological information should be held for all listable disinfectants, according to the requirements outlined by any relevant state or federal environmental protection legislation. The information provided should be reflected in appropriate handling, storage, transport, use, disposal, waste management and neutralisation instructions. The potential for reuse or recycling should be considered whenever appropriate.

Packaging

The container for a disinfectant must:

- be impervious to and incapable of reacting with its contents
- be sufficiently strong to prevent leakage arising from ordinary risks of handling, storage or transport, and
- have sufficient excess capacity to prevent breakage of the container or leakage of the contents if the contents are likely to expand during handling, storage or transport.

Note

Depending on the ingredients of your product, you may also need to comply with the requirements of the Poisons Standard (the SUSMP) and the Australian Dangerous Goods Code.

Labelling

All listed disinfectants must have labelling in place that includes the following:

- Approved name(s) of all ingredients that are active against pathogenic or food spoilage micro-organisms
- acceptable common name of the disinfectant (Schedule 3 TGO X)
- quantity/proportions of ingredients(s) which result or contribute to the disinfectant action, and proportion of available chlorine/bromine/iodine if applicable
- quantity of disinfectant
- batch number
- expiry date or use by date
- the AUST L number[1]
- name and address of the manufacturer or sponsor
- the chemical and physical specifications of the formulation of the product
- clear and adequate instructions for use, including:
  - details on how to prepare the disinfectant and use it to ensure specifications are met, including details on: type of diluent, the required strength, and any limitations on quality, contact time, allowable temperature range, minimum effective concentration and pH range if significant
  - installation instructions (if applicable)
  - limitations of use, including reuse period (if applicable) and managing dilution factor if disinfectant is reused
  - where reuse is provided for, complete information on how to properly monitor the effectiveness of the reused solution (use of test strips), and
  - limitations on storage conditions for stock solutions and activated solution.
- The words:
  - 'Hard surface disinfectant only', and
  - 'Not to be used on skin'.

[1] Disinfectant products transitioning from Registered to Listed will change from an AUST R number to an AUST L number. A transition period to 31 December 2019 is proposed, to enable sponsors to consume current packaging stocks.

For hospital grade:

– Not intended to be used on medical devices or other therapeutic goods

> **Note**
>
> Household grade disinfectants and commercial grade disinfectants **must not** be labelled “hospital grade” or use words implying that they are hospital grade.

Making an application

Applications for multiple products

Many sponsors have a range of listed disinfectants in different presentations, or may sell differently branded versions of the same product. Generally these products are considered to be separate and distinct therapeutic goods under section 16 of the Act and therefore require individual listing on the ARTG.

Listed disinfectants are able to be treated as a single therapeutic good if they have the following common characteristics:

- the sponsor
- the principal manufacturer
- they are disinfectants with specific claims
- supply in the same state of sterility, whether sterile or non-sterile
- are not subject to different standards, and
- contain the same ingredient that is active in their final formulation.

If your listed disinfectants meet these requirements, you can apply for listing of these goods with one application.

For further information refer to the Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991.

If you wish to enter additional goods that come within the requirement of the Single Goods Order onto an existing ARTG entry, you can request a variation of the listing of your therapeutic goods. This can be done by submitting a Device Change Request, which will be considered by the Delegate of the Secretary under section 9D of the Act.

Note

One Device Change Request can be submitted for additional products providing the products share common characteristics as defined in the *Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991*, and the only variation is in presentation of the goods and/or packaging/branding.

If the composition of the goods has changed (i.e. you are now manufacturing/supplying a listed disinfectant that has a different ingredient that is active), this is not a variation and you will need to submit an application for a separate listing of these goods on the ARTG.

Supporting information

You will need to retain the following information in case it is requested by the Secretary or their delegate:

- Labels
- Packaging (a simple characterisation or pictorial images of the container used should be provided for products subject to evaluation. Mention should be made of any unusual features and of those provided to comply with the SUSMP or elsewhere)
- Test Certificates to support new ingredients or specific claims, for each batch of disinfectants prior to supply in Australia. The term "specific claims" therefore applies to virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity and activity against bacteria other than those consistent with the characteristics of organisms covered by the TGA Disinfectant Test
- Formulation of stock disinfectant and for any dilutions or activated compounds specified on the labelling, and
- The chemical and physical specifications for the formulation.

Note

Evidence to demonstrate compliance with (*the proposed*) TGO X must be held by the manufacturer or sponsor for examination on request in the event of a problem arising with the product or as part of a routine compliance evaluation. This guidance is relevant only in so far as there is a requirement to be met in the proposed TGO X.

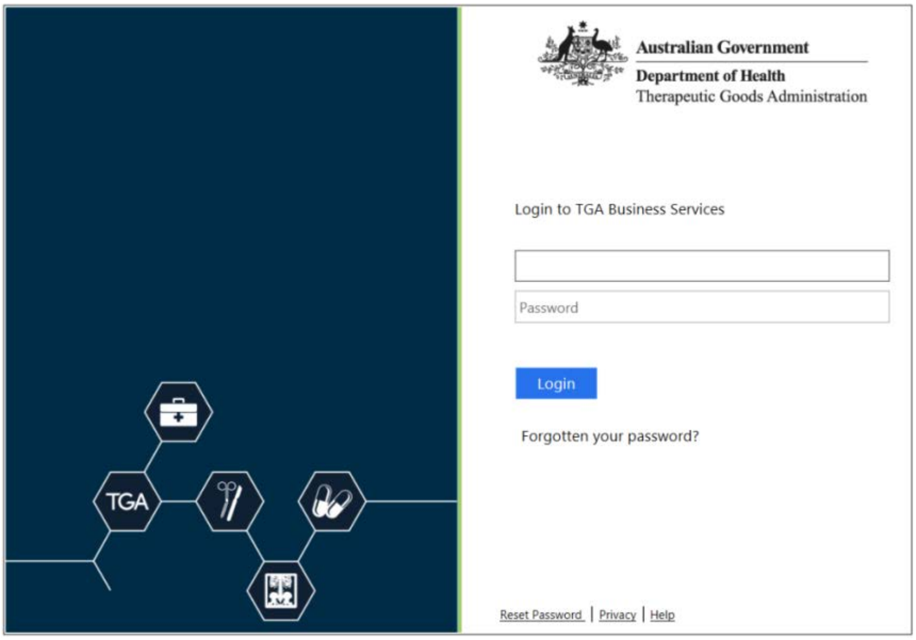
Submitting your application

To submit your application for your disinfectant to be listed on the ARTG, you will need access to the TGA's Business Services system (TBS).

You need to login into your TBS account to access the application forms. If you don't have an account/access, follow the instructions at TGA Business services: getting started with the TGA.

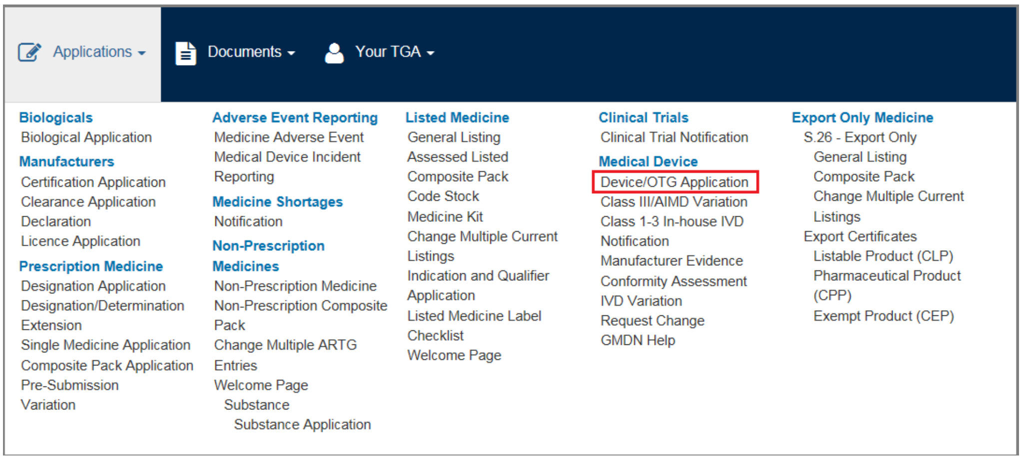
Step 1 - Login to TGA Business Services

Enter your user name and password.



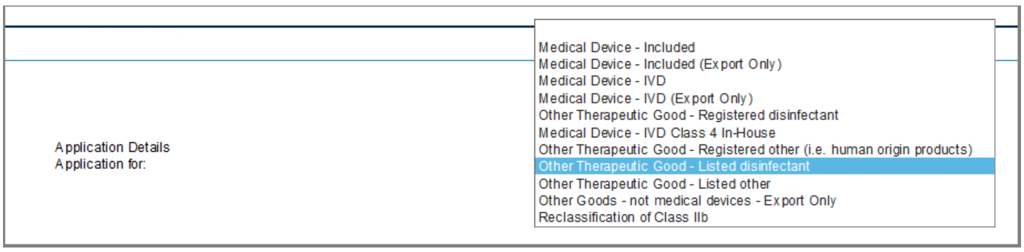
Step 2 - Select the relevant application type

From the Applications menu, under the Medical Device list, select ***Device/OTG Application***.



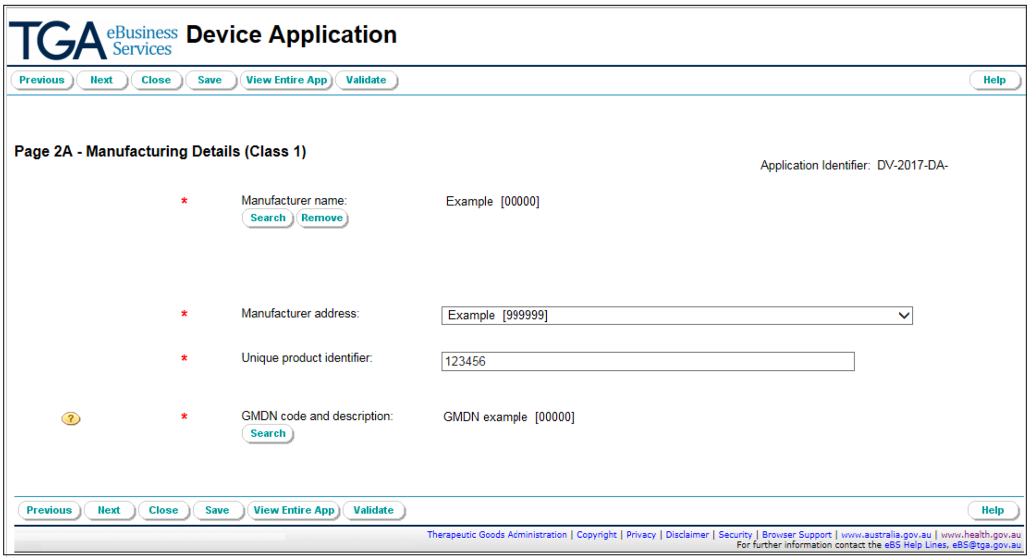
Step 3 – Complete the application form and attach all relevant documents

You'll be taken to Page 1 of the application form to complete/confirm the required details. To begin, select ***Other Therapeutic Good – Listed disinfectant*** from the list in the ***Application for*** field.

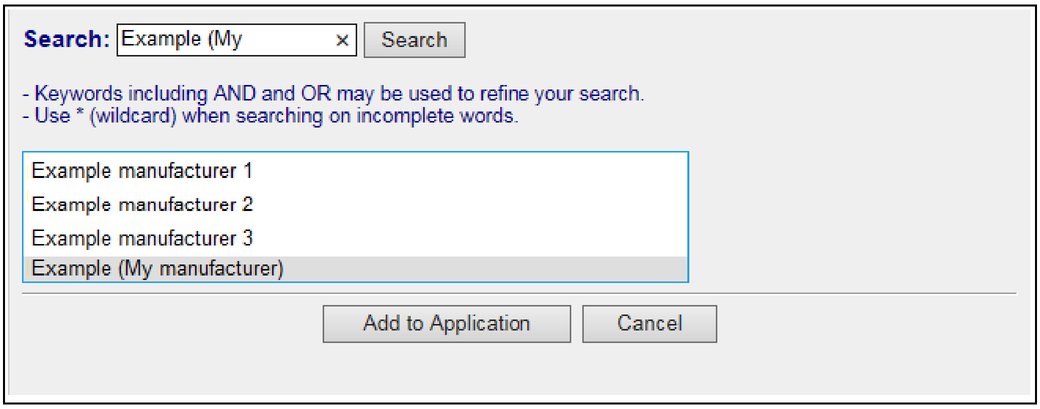


Complete the required details for Page 1, remembering to add a Sponsor's own reference before continuing. Select the ***Next*** button to continue.

Page 2 requires the relevant manufacturer's details.



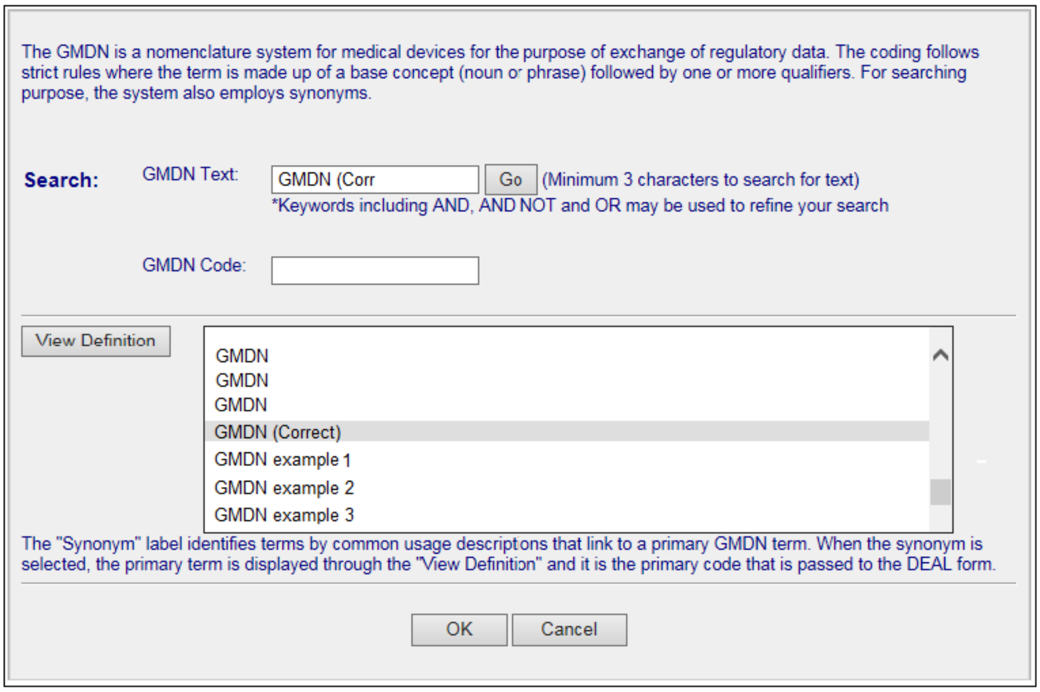
To search for your manufacturer, select the ***Search*** button under ***Manufacturer name*** which opens the search window.



Enter your search term and select the ***Search*** button. This will display a list of possible manufacturers which match (or closely match) your search term.

Once you have selected the correct manufacturer, select the ***Add to Application*** button.

To select the correct GMDN code for your application, select the ***Search*** button under the ***GMDN code and description*** field which will open the ***GMDN search*** window.



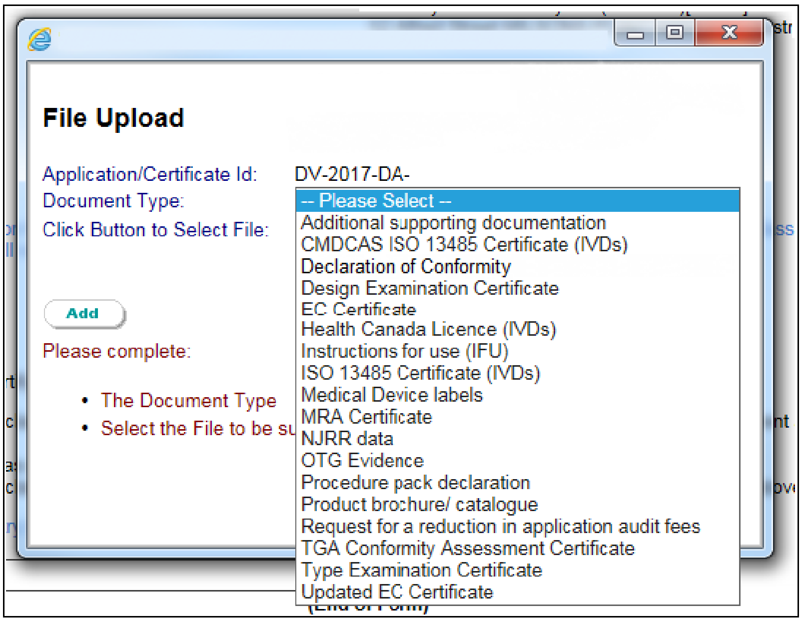
You can search by the GMDN code, or text in the GMDN description. Once you have found the correct GMDN, select it from the search results, and press ***OK*** to add the details to your application. Once you have completed Page 2, select ***Next*** to continue.

The final page has a:

- summary of the application information for you to review
- section to electronically attach supporting information
- declaration you need to agree to before you can submit your application.

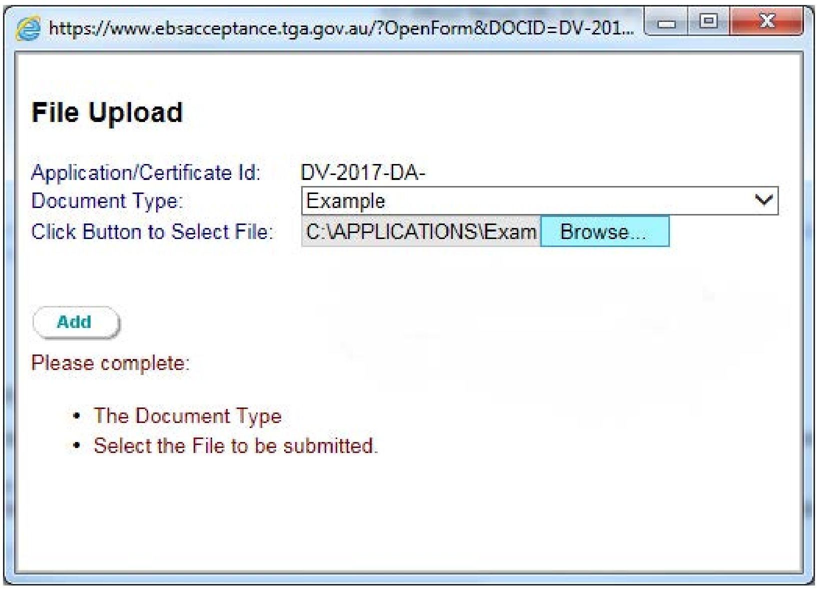
Attaching supporting documents

To attach supporting information, select the ***Add*** button in the ***Function to Attach/Add Supporting Information*** field which will open the ***File Upload*** window.



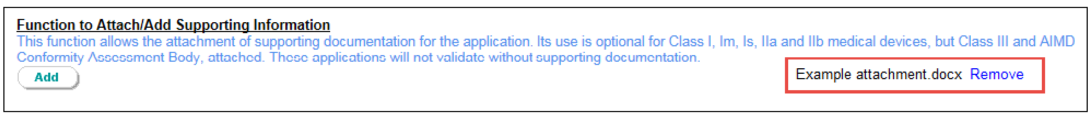
Select the Document type from the dropdown list. You should attach all relevant documents from your computer. Select the Browse button and then select the relevant file from your computer to attach. Select the Add button to attach this file to your application.

Note: Follow this process for each file you need to attach.

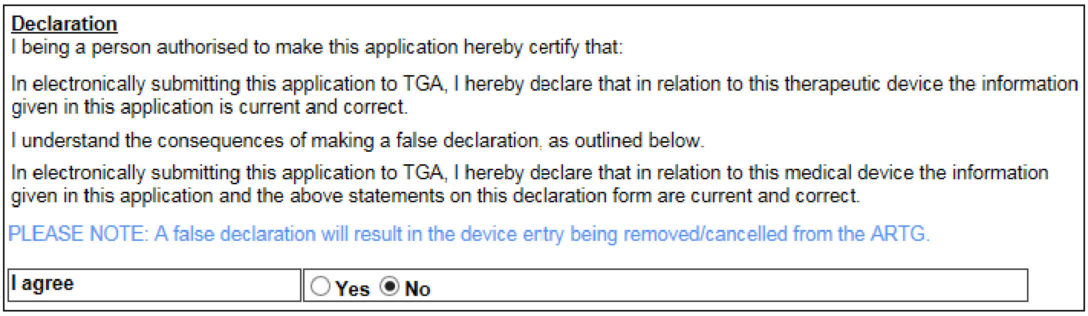


Each attachment will be listed under the ***Function to Attach/Add Supporting Information*** field.

If you need to delete any attachments, select ***Remove*** next to the attachment you want to delete.



Before you can submit your application, you must agree to the declaration:


Declaration

I being a person authorised to make this application hereby certify that:

In electronically submitting this application to TGA, I hereby declare that in relation to this therapeutic device the information given in this application is current and correct.

I understand the consequences of making a false declaration, as outlined below.

In electronically submitting this application to TGA, I hereby declare that in relation to this medical device the information given in this application and the above statements on this declaration form are current and correct.

PLEASE NOTE: A false declaration will result in the device entry being removed/cancelled from the ARTG.

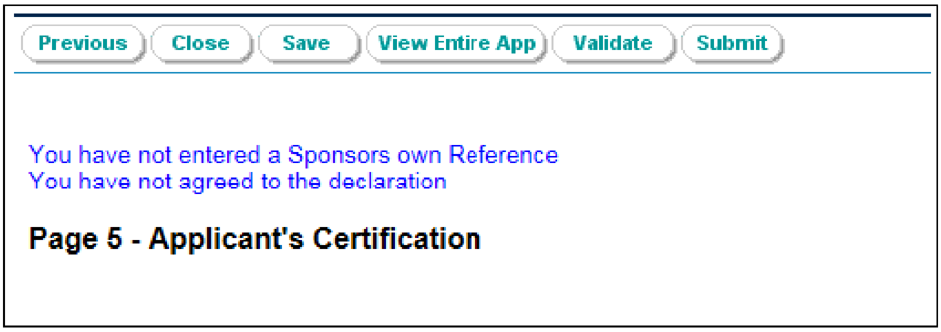
I agree	Yes No

When the form has been completed, select ***Validate***. This will ensure that the form has all the required information to allow your form to be submitted.

Note

Validation of your form is only confirming that you have filled out all required fields in the application. Validation is not an approval of your application or a guarantee that all the required information has been submitted to the TGA.

If there are any issues with the form, they will be identified with blue writing near the top of the page that will link you to the incomplete information when you select it.


Previous | Close | Save | View Entire App | Validate | Submit

You have not entered a Sponsors own Reference
You have not agreed to the declaration

Page 5 - Applicant's Certification

If you filled in all required fields in the application form, you will be able to submit your application.

Fees and charges

Application fee

The current application fee for listed disinfectants can be found in our [Schedule of fees and charges] under "Other listed and registered therapeutic goods (OTGs)". The application fee is specifically stated under "Listed OTG fees" as "Application fee".

Evaluation fee

Listed disinfectants may attract an evaluation fee in addition to the initial application fee if they contain a new ingredient or make new specific claims. The current evaluation fee can be found in our [Schedule of fees and charges] under "Other listed and registered therapeutic goods (OTGs)".

The fee is specifically stated under "Listed OTG fees" as "Fee for evaluating documents and information relating to the safety of a listed therapeutic device."

> **Note**
>
> Application and evaluation fees are not refundable. For further information refer to the refunds webpage.

Annual charges

Once your product is listed on the ARTG, annual charges for maintaining your listing will apply. The current annual charge for listed disinfectants can be found in our Schedule of fees and charges under "Other listed and registered therapeutic goods (OTGs)". The fee is specifically stated under "Annual charges" as "Listed OTG: tampons and disinfectants".

Post market – ongoing responsibilities

Once a disinfectant has been listed on the ARTG, it must continue to meet all the regulatory, safety and performance requirements and standards that were required for the approval.

There are mandatory requirements for all sponsors of disinfectants, including:

- telling us about any changes:
  - that relate to the manufacture, formulation, claims or labelling of disinfectants, or
  - to the composition of your product, and
- ensuring the information on your ARTG listing remains current.

This section should be read in conjunction with:

- Appendix 4: Conditions – standard and specific – *(Applying to registered or listed therapeutic goods under Section 28 of the Therapeutic Goods Act 1989.)*
- Reporting adverse events:

Sponsors of Registered or Listed disinfectants are required to provide:

- information that indicates that the use of the goods in accordance with the recommendations for their use may have an unintended harmful effect
- information that indicates that the goods, when used in accordance with the recommendations for their use, may not be as effective.

> **Note**
>
> Sponsors of disinfectants should report adverse events relating to your product at Report a medical device adverse event (sponsor/manufacturer).

Version history

Version	Description of change	Author	Effective date
V1.0	Consultation version	Therapeutic Goods Administration, Medical Devices Branch	18/12/2018

Therapeutic Goods Administration

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